REMARKS

Claim 6 was rejected under 35 USC 112, second paragraph as being redundant. Claim 6 has been cancelled.

OK to enter 5/23/03

The Examiner indicates that Figures 8a-8C were not included with the filing of the present application. Applicant has included a full set of drawings, including those indicated as missing and respectfully requests that they be added to the file. No new matter has been added. Applicant also notes that Provisional application 60/191,075, was filed on March 21, 2000 and the present application claims the benefit of that provisional filing. By the present amendment, the Provisional application has been formally incorporated by reference and forms an alternative basis to introduce the Figures, which were submitted with the provisional filing.

Claims 1, 3, 4 and 6-9 were rejected under 35 USC 102(b) as being anticipated by Gunderson. Claims 5, 10 and 11 were rejected under 35 USC 103(a) as being unpatentable over Gunderson in view of Rossing. These rejections are respectfully traversed.

By the above amendments, claim 3 has been cancelled and its elements added to independent claim 1. Claims 4 and 5 have been rewritten in independent form and include all of the elements of former claim 1. Applicant respectfully asserts that the amended claims are allowable over the references of record.

Gunderson teaches a method and apparatus for discriminating between tachycardia and fibrillation that measures the intervals separating depolarizations, sorts the intervals into ranges and based on the distribution of ranges, identifies tachycardia or fibrillation. The reference fails to teach "means for defining a discrimination criterion based on determining whether designated ones of the plurality of interval range bins have at least a predetermined threshold number of measured depolarization intervals within them." Specifically, the reference fails to teach an apparatus wherein "the threshold number is set as

a value which increases as an inverse function of the length of the intervals between depolarizations," as specified in claim 1.

Likewise, the reference fails to teach an apparatus "wherein the threshold number is set as a value which increases as an inverse function of a defined percentile of the length of intervals over a sequence of a predetermined number of intervals between depolarizations," as specified in claim 4. Nor does the reference teach an apparatus wherein the "threshold number is set as a value which increases as an inverse function of the 75th percentile of the length of intervals over a sequence of a predetermined number of intervals between depolarizations," as specified in claim 5. These particular threshold determinations serve to further increase the accuracy of the arrhythmia determination. As such, Gunderson fails to anticipate these claims.

With respect to amended claims 1 and 4, the Examiner asserts that these elements are shown in Gunderson at Col 2, line 63 to Col 3, line 25. A careful reading of these sections clearly indicates that such teachings are absent. That is, Gunderson does teach sorting events into bins and making a determination as to the particular arrhythmia; however, there is no teaching as to setting the threshold number based on inverse functioning criteria presently claimed.

With respect to claim 5, the Office Action indicates that Gunderson fails to teach "the threshold value increasing as a function of the 75^{th} percentile of the length of the intervals of a predetermined number of intervals." The Examiner then asserts that Rossing provides such a teaching.

As previously discussed, Rossing discloses a technique wherein a programmable fibrillation detection interval range and a programmable tachycardia detection interval range are adjacent to one another. In particular, the interval range designated as indicative of fibrillation consists of intervals less than a programmable interval (FDI) and the interval range designated as indicative of ventricular tachycardia consists of intervals less than a programmable interval (TDI) and greater than or equal to FDI. Measured R-R intervals, out of a preceding series of a predetermined number (FEB) of intervals,

falling within each of these two ranges are separately counted. That is, a count (VTEC) of R-R intervals falling within the tachycardia interval range, and a count (VFEC) of the number of intervals falling within the fibrillation interval range are made. VTEC is incremented in response to R-R intervals that are greater than or equal to FDI but shorter than TDI, and is reset to zero in response to intervals greater than or equal to TDI and is insensitive to intervals less than FDI. VTEC is compared to a programmed value (VTNID) and VFEC is compared to a corresponding programmable value (VFNID). When one of the counts equals its corresponding programmable value, the criterion for the presence of the corresponding arrhythmia, i.e. fibrillation or tachycardia, is met. An appropriate therapy, e.g. anti-tachycardia pacing, a cardioversion pulse or a defibrillation pulse, is then delivered. Whereas Rossing discriminates on the basis of determining which of two interval ranges has the most counts, the present invention examines the relative distribution of the measured depolarization intervals.

The Examiner appears to have focused on the binary criteria disclosed by Rossing that indicates when one of the other of the intervals has been satisfied. That is, if, for example, 50% or 75% of the recorded events fall within a given interval, then the appropriate counter is incremented (Col. 4, lines 4-17). This does not teach an apparatus wherein the "threshold number is set as a value which increases as an inverse function of the 75th percentile of the length of intervals over a sequence of a predetermined number of intervals between depolarizations," as specified in claim 5. As such, this reference fails to remedy the deficiencies noted in Gunderson.

In consideration of the amendments to the claims and the remarks presented herein, Applicant submits that all pending claims are now in condition for allowance and requests that a notice of allowance issue in due course.

Respectfully submitted,

5/12/03
Date

Atty: Daniel G. Chapik
Reg. No. 43,424
(763) 514-3066

27581

A New VT/VF Discriminator for Implant

Robert W. Stadler, PhD, Bruce D. Gunderson. MS. Jeffrey M
Medtronic Inc. Minneapoli

A New VT/VF Discriminator for Implantable Cardioverter Defibrillators
Robert W. Stadler, PhD, Bruce D. Gunderson, MS, Jeffrey M. Gillberg, MS, Walter H. Olson, PhD,
Medtronic Inc, Minneapolis, MN

BACKGROUND: Accurate discrimination of ventricular tachycardia (VT) from ventricular fibrillation (VF) by implantable cardioverter defibrillators (ICDs) is desired to avoid delivery of shocks for arrhythmias that can be terminated by anti-tachycardia pacing (ATP).

METHODS: A new discriminator algorithm that considers the regularity and the 75th percentile of cycle length was designed empirically from a database of 107 VFs and 203 VTs (43% induced and 57% spontaneous). The gold standard classification of VT or VF was made by a panel of experts from ventricular far-field EGM and surface ECG when available. The regularity parameter, the "modesum", was the percentage of beats falling in the 3 most commonly occurring ventricular cycle lengths (18-sec bins) among the last 18 cycle lengths. VT/VF discrimination was achieved by comparing the calculated modesum to a threshold which decreased linearly as the 75th percentile cycle length of arrhythmias increased. Ventricular arrhythmias that achieved VF rate criteria, were slower than an upper cutoff rate, and surpassed the modesum threshold for their rate were classified as VT. Thus, more regularity was required for faster VTs to be classified as VT, and only the fastest and most irregular VTs, which are unlikely to respond to ATP, were classified as VF by the new discriminator.

RESULTS: Performance of the new discriminator, the Fast VT via VF algorithm, all ventricular ICDs, and a simple rate discriminator were evaluated on a separate database of 244 VFs and 325 VTs (54% Induced and 46% spontaneous). To facilitate direct performance comparisons, 99% VF sensitivity was maintained for each discriminator by adjusting the upper rate cutoff for classification as VT. Rhythms that were faster than the upper cutoff were always classified as VF.

VT/VF Discriminator	VT Sensitivity	VF Sensitivity	Upper Rate Cutoff
New Discriminator	83%	99%	240 bpm
Fast VT via VF	71%	99%	222 bpm
Simple Rate Discriminator	34%	99%	176 bpm

CONCLUSION: The new VT/VF discriminator improved VT sensitivity and could therefore decrease the number of unnecessary shocks by almost 50% over simple rate discriminators and by 12% over the FVT via VF algorithm.

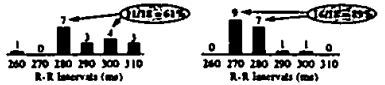
INTRODUCTION

- The majority of VTs can be terminated painlessly by anti-tachycardia pacing (ATP), yet VTs are often detected as VF and treated inappropriately with shocks.
- Mean or median cycle lengths are a poor discriminator of VT from VF.
- Advanced discriminators of VT from VF are necessary to decrease the delivery of shocks for arrhythmias that can be terminated by ATP.

EXISTING VT/VF DISCRIMINATORS

All of the discriminators have a "short interval threshold." Cycle lengths that are shorter than the short interval threshold lead to classification of VF. Selection of the short interval threshold is a tradeoff between VT sensitivity and VF sensitivity.

- Simple Rate Discriminator: If 75% of the cycle lengths are shorter than a programmable short interval threshold (the VF threshold), classify the rhythm as VF.
- Medtronic Fast VT via VF algorithm:
  - If the arrhythmia achieves VF rate criteria but the last 8 cycle lengths before VF detection are longer than a programmable short interval threshold, the episode is classified as a Fast VT rather than VF.
- Medtronic Jewel AF™ VT/VF Discriminator:
  - Compute the "Modesum" from a histogram of the last 18 cycle lengths before standard VF detection. The Modesum, a measurement of regularity, is the sum of the two largest bins in the cycle length histogram:



  - Intervals shorter than a fixed short interval threshold of 240 ms are excluded from the Modesum calculation (but the denominator remains 18).
  - If the Modesum is > 13/18 (72%), classify as Fast VT rather than VF.

DATABASES

Algorithm Development Database:
107 VFs and 203 VTs (43% Induced and 57% Spontaneous) from 95 patients. Spontaneous episodes were obtained from the GEM DR™ clinical study. Spontaneous episodes that received therapy before the 18th cycle of the arrhythmia were excluded.

Performance Evaluation Database:
244 VFs and 325 VTs (54% Induced and 46% Spontaneous) from 161 patients. The patients that contributed to the Algorithm Development Database did not contribute to the Performance Evaluation Database. Spontaneous episodes were obtained from the GEM DR™ clinical study. Spontaneous episodes that received therapy before the 18th cycle of the arrhythmia were excluded.

Determination of the Gold Standard Classification:
Classification as VT or VF was made by a panel of experts from ventricular far-field EGM and surface ECG when available. Polymorphic VT was classified as VT and ventricular flutter was classified as VF.

THE NEW VT/VF DISCRIMINATOR

For arrhythmias that achieve VF detection criteria:

- Compute the Modesum from a histogram of the last 18 cycle lengths before VF detection. Intervals shorter than a programmable short interval threshold are excluded from the Modesum calculation (but the denominator remains 18).
- Compute the 75th percentile of cycle lengths for the arrhythmia (i.e., the 4th longest interval out of the last 12).
- Classify the arrhythmia as VT if the Modesum exceeds a threshold which decreases linearly as the 75th percentile of cycle lengths increases.

Figure 1 is a scatterplot of the Modesum and the 75th percentile of cycle lengths for arrhythmias from the Algorithm Development Database. The design of the New VT/VF Discriminator is also displayed in Figure 1. The short interval threshold for this Figure is the minimum value of 120ms.

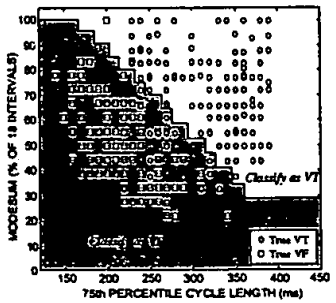


Figure 1: A scatterplot of arrhythmias from Algorithm Development Database and the design of the New Discriminator for the case with the minimum short interval threshold (120 ms).

RESULTS

Figures 2 and 3 are scatterplots of arrhythmias in the Per
Database for short interval thresholds of 120 ms and 240
Very few VTs or VFs were misclassified by the algorithm
classification of VFs improved when the short interval th
switched from 120 ms in Figure 2 to a more realistic valu
Figure 3.

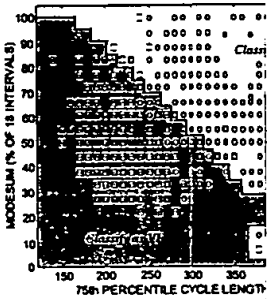


Figure 2: A scatterplot of arrhythmias from the Performance
and the performance of the New Discriminator for the case w
short interval threshold (120 ms).

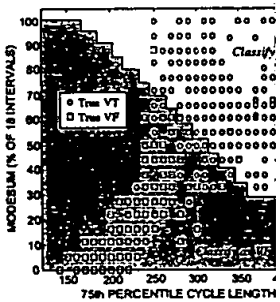


Figure 3: Performance of New Discriminator on the Perfo
Database when the short interval threshold was 240 ms.